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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,677	03/25/2005	Felix Ecker	Le A 35 839	2331

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,677	ECKER ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/19/2005 AND 07/16/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over USP 6,773,724 in view of WO 1999/008659.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference discloses a composition of matter comprising salt crystals formed by combining o-acetylsalicylic acid with a basic amino acid (e.g., lysine), wherein said salt crystals have an average particle size above about 170 micrometers, wherein more than about 70% of the crystals in said composition have a particle size

from about 100 micrometers to about 200 micrometers, wherein said particle size is measured by laser diffraction (claims 1-6 and 20-21).

The compositions according to the invention can be employed as analgesics, antipyretics, antirheumatics, and also as non-steroidal anti-inflammatory agents, for example for the treatment of diseases of the rheumatic type, neuralgia, myalgia, and migraine. In particular, however, they can also be employed as platelet aggregation inhibitors in the prevention and therapy of cardiovascular and cerebrovascular diseases (e.g. in ischemic heart diseases, stroke, stable and unstable angina pectoris, acute myocardial infarct, bypass operations, PTCA, stent implantation). Further application areas are stimulation of the immune system in HIV patients and tumor prophylaxis (e.g. carcinoma of the colon, esophagus or lung), slowing of the cognitive deterioration in dementia syndrome (e.g. Alzheimer's disease), inhibition of gallstone formation and the treatment of diabetic diseases. (See paragraph bridging columns 4 and 5.)

The primary reference does not disclose adding flow enhancing agents or roller compression.

The WO document, although it does not expressly teach a composition comprising aspirin and basic amino acids, does discloses a method of improving flow and compression of flowable tableting compositions (title; abstract) by adding sugar alcohols (e.g., mannitol, xylitol, etc. - page 7, lines 13-16) to attain a cohesive and self-binding property and by densifying, which includes the preferred method of roller compression (page 15, lines 20-23). The composition has the advantage of having cohesive properties (abstract).

It would have been obvious to the skilled artisan to add xylitol and to use roller compression to make the patented composition. The motivation would have been to improve flow and compression of a flowable tableting composition.

Claims 1-19 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 10/915,652 which has a common assignee with the instant application, taken in view of WO 1999/008659. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application.

This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. This rejection might also be overcome by showing that the copending application is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference discloses a composition of matter comprising salt crystals formed by combining o-acetylsalicylic acid with a basic amino acid (e.g., lysine), wherein said salt crystals have an average particle size above about 170 micrometers,

wherein more than about 70% of the crystals in said composition have a particle size from about 100 micrometers to about 200 micrometers, wherein said particle size is measured by laser diffraction (claims 22-30).

The compositions according to the invention can be employed as analgesics, antipyretics, antirheumatics, and also as non-steroidal anti-inflammatory agents, for example for the treatment of diseases of the rheumatic type, neuralgia, myalgia, and migraine. In particular, however, they can also be employed as platelet aggregation inhibitors in the prevention and therapy of cardiovascular and cerebrovascular diseases (e.g. in ischemic heart diseases, stroke, stable and unstable angina pectoris, acute myocardial infarct, bypass operations, PTCA, stent implantation). Further application areas are stimulation of the immune system in HIV patients and tumor prophylaxis (e.g. carcinoma of the colon, esophagus or lung), slowing of the cognitive deterioration in dementia syndrome (e.g. Alzheimer's disease), inhibition of gallstone formation and the treatment of diabetic diseases. (See paragraph [0036].)

The primary reference does not disclose adding flow enhancing agents or roller compression.

The WO document, although it does not expressly teach a composition comprising aspirin and basic amino acids, does discloses a method of improving flow and compression of flowable tableting compositions (title; abstract) by adding sugar alcohols (e.g., mannitol, xylitol, etc. - page 7, lines 13-16) to attain a cohesive and self-binding property and by densifying, which includes the preferred method of roller

compression (page 15, lines 20-23). The composition has the advantage of having cohesive properties (abstract).

It would have been obvious to the skilled artisan to add xylitol and to use roller compression to make the patented composition. The motivation would have been to improve flow and compression of a flowable tableting composition.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 and 15-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 and 20-21 of U.S. Patent No. 6,773,724 in view of WO 1999/008659. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are

embraced by the patented claims. The patent does not claim the composition containing flow enhancers.

The WO document, although it does not expressly teach a composition comprising aspirin and basic amino acids, does discloses a method of improving flow and compression of flowable tableting compositions (title; abstract) by adding sugar alcohols (e.g., mannitol, xylitol, etc. - page 7, lines 13-16) to attain a cohesive and self-binding property and by densifying, which includes the preferred method of roller compression (page 15, lines 20-23). The composition has the advantage of having cohesive properties (abstract).

It would have been obvious to the skilled artisan to add xylitol and to use roller compression to make the patented composition. The motivation would have been to improve flow and compression of a flowable tableting composition.

Claims 1-11 and 15-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-30 of copending Application No. 10/915,652 in view of WO 1999/008659. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are embraced by the claims of the copending application. The copending application does not claim the composition containing flow enhancers.

The WO document, although it does not expressly teach a composition comprising aspirin and basic amino acids, does discloses a method of improving flow and compression of flowable tableting compositions (title; abstract) by adding sugar

alcohols (e.g., mannitol, xylitol, etc. - page 7, lines 13-16) to attain a cohesive and self-binding property and by densifying, which includes the preferred method of roller compression (page 15, lines 20-23). The composition has the advantage of having cohesive properties (abstract).

It would have been obvious to the skilled artisan to add xylitol and to use roller compression to make the composition of the copending application. The motivation would have been to improve flow and compression of a flowable tableting composition.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Chris E Simmons/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612